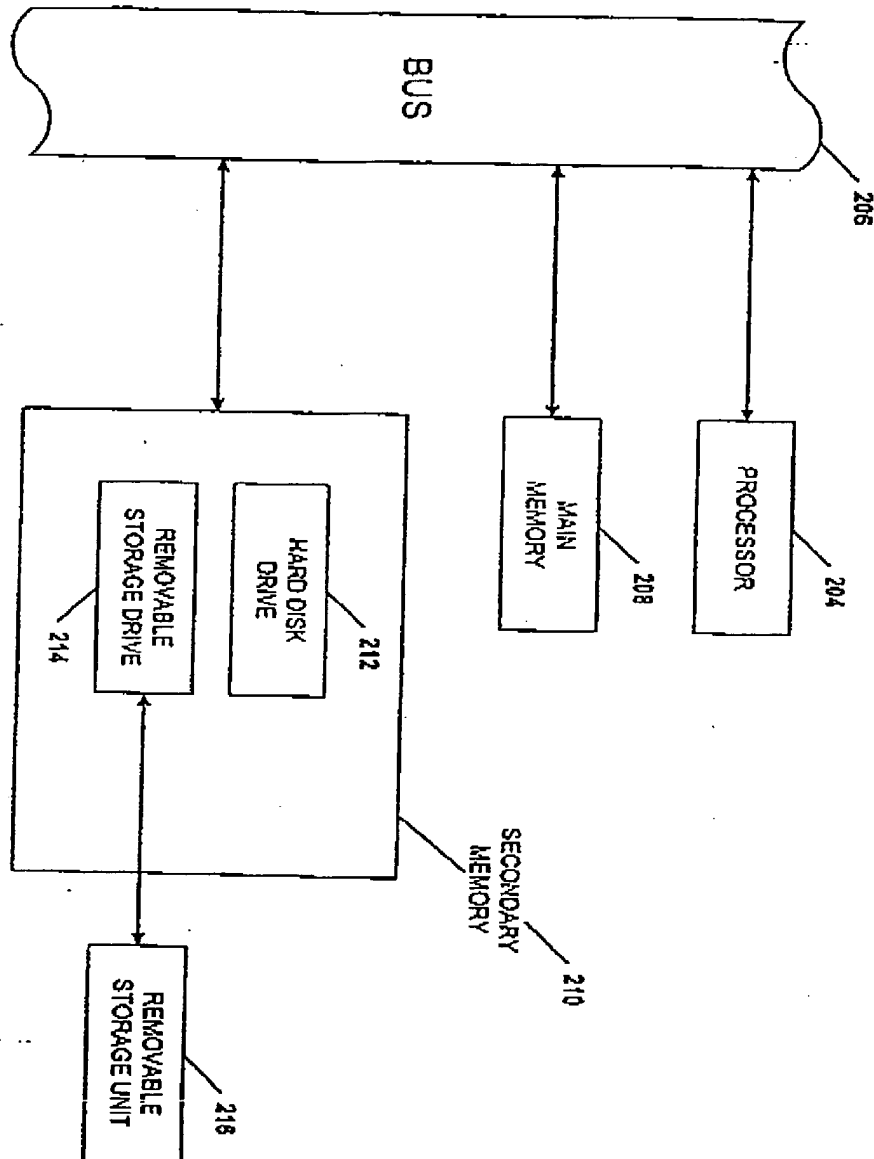




BEST AVAILABLE COPY

FIG. 1



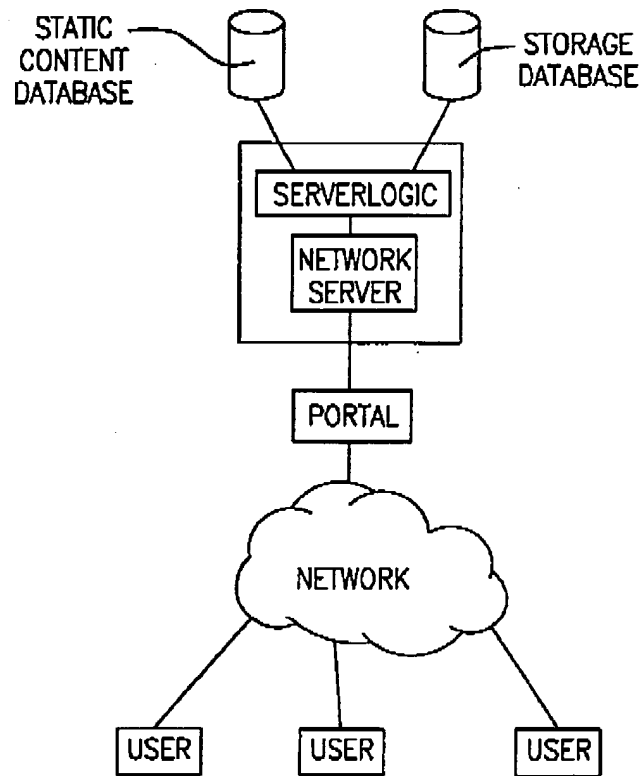


FIG. 2

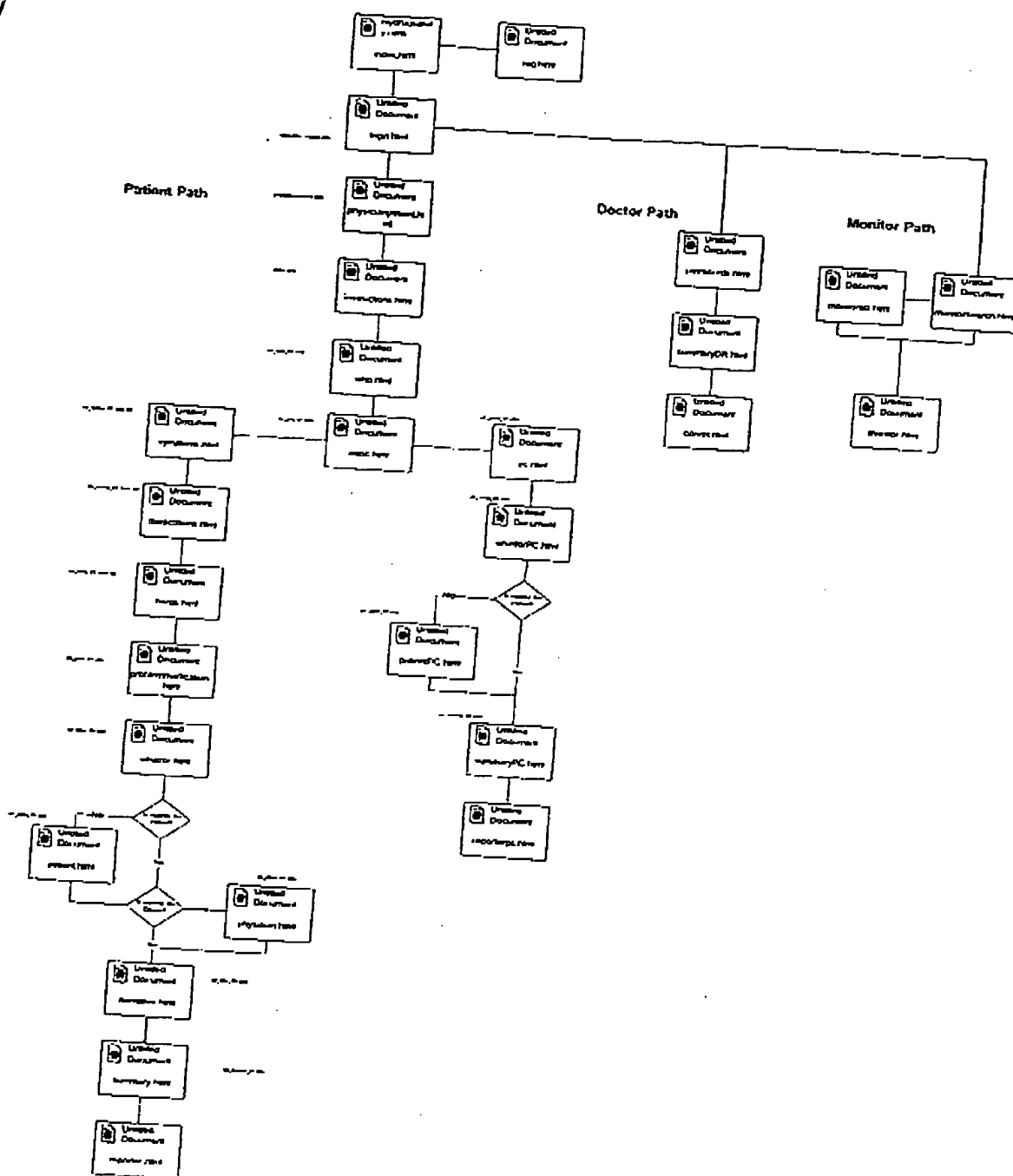


FIG. 3



### Portal Pilot Workflow

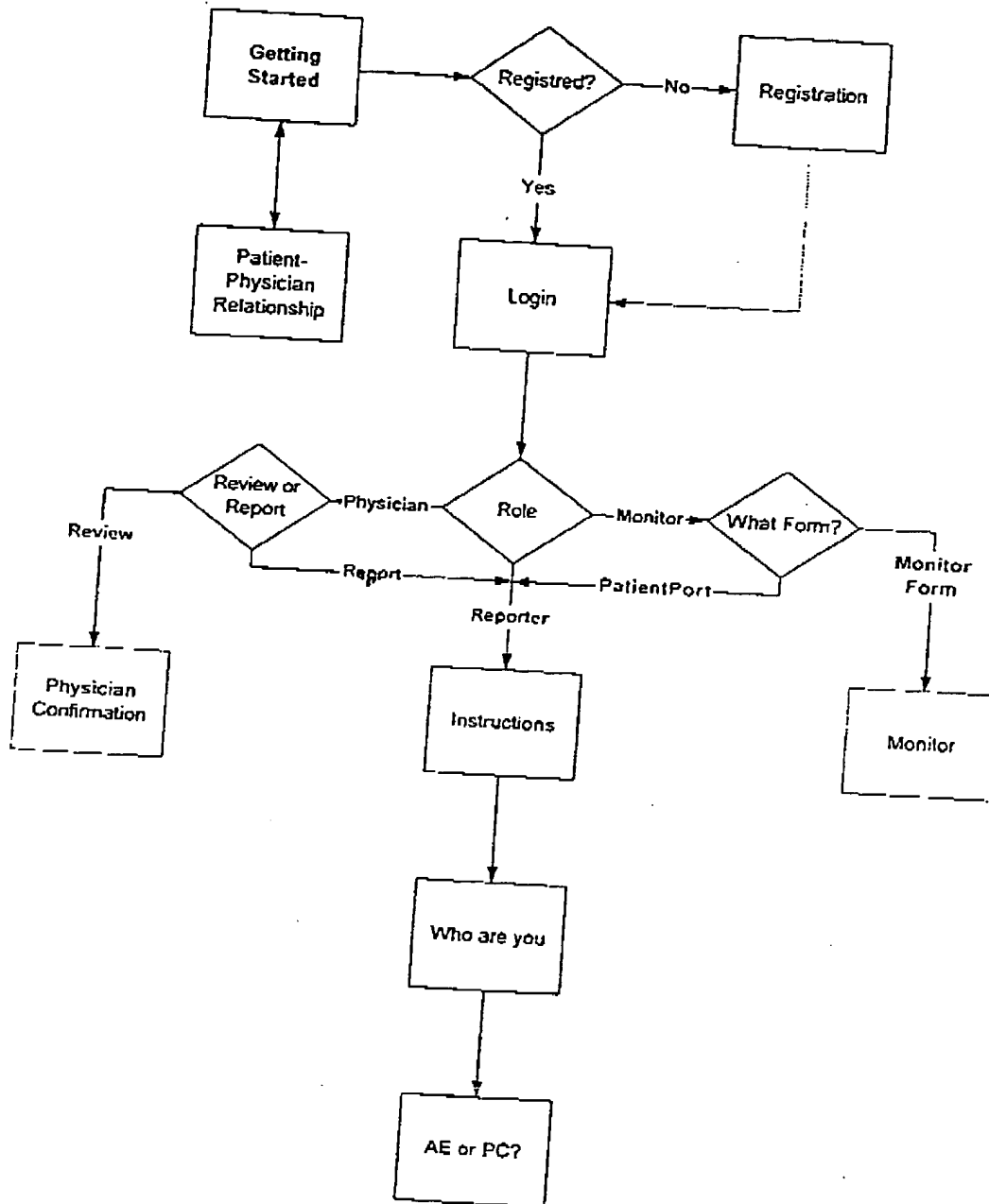
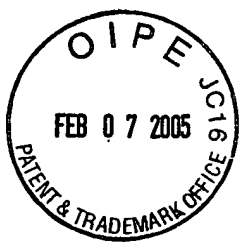


FIG. 3A



### AE or PC Guided Reporting

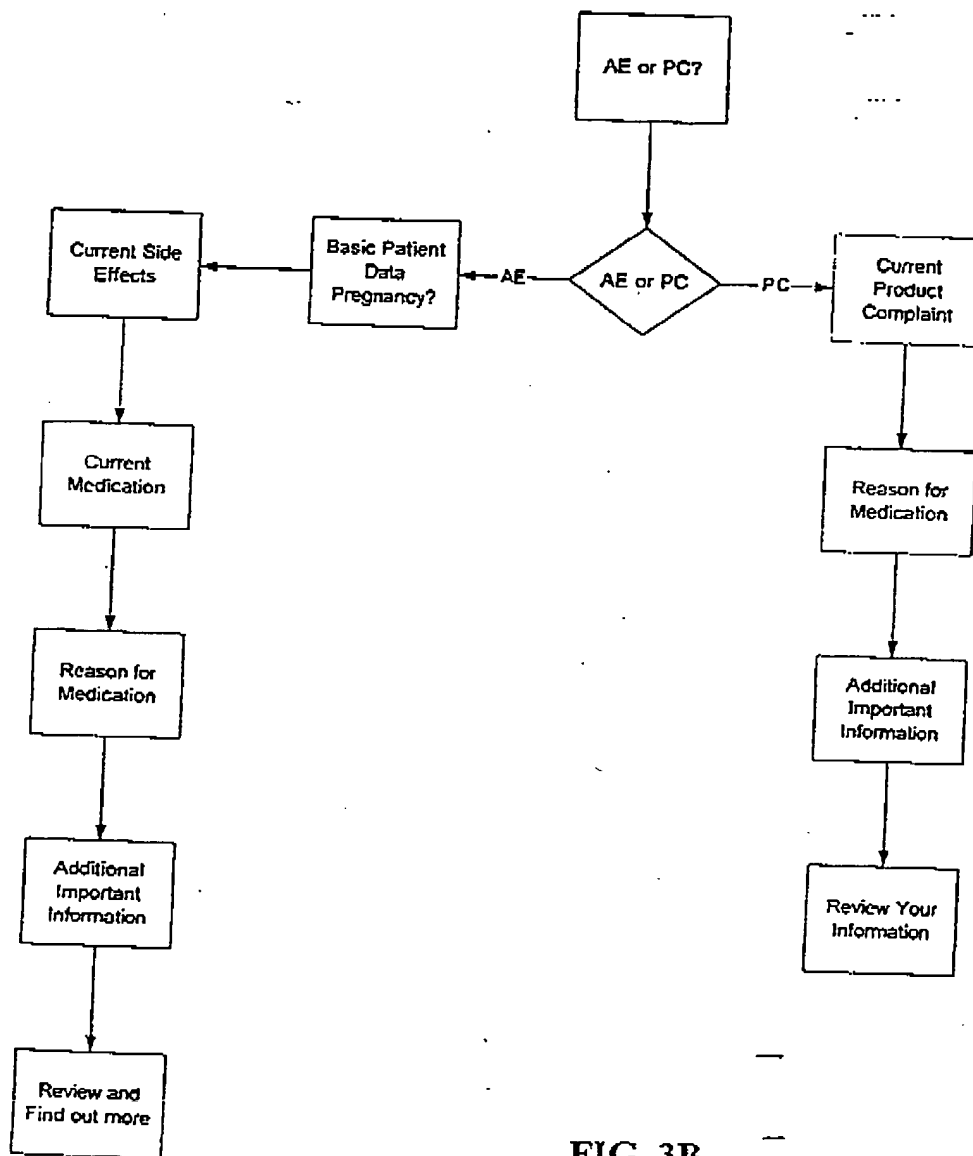
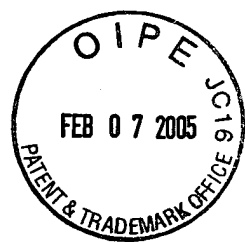


FIG. 3B



## Physician Confirmation

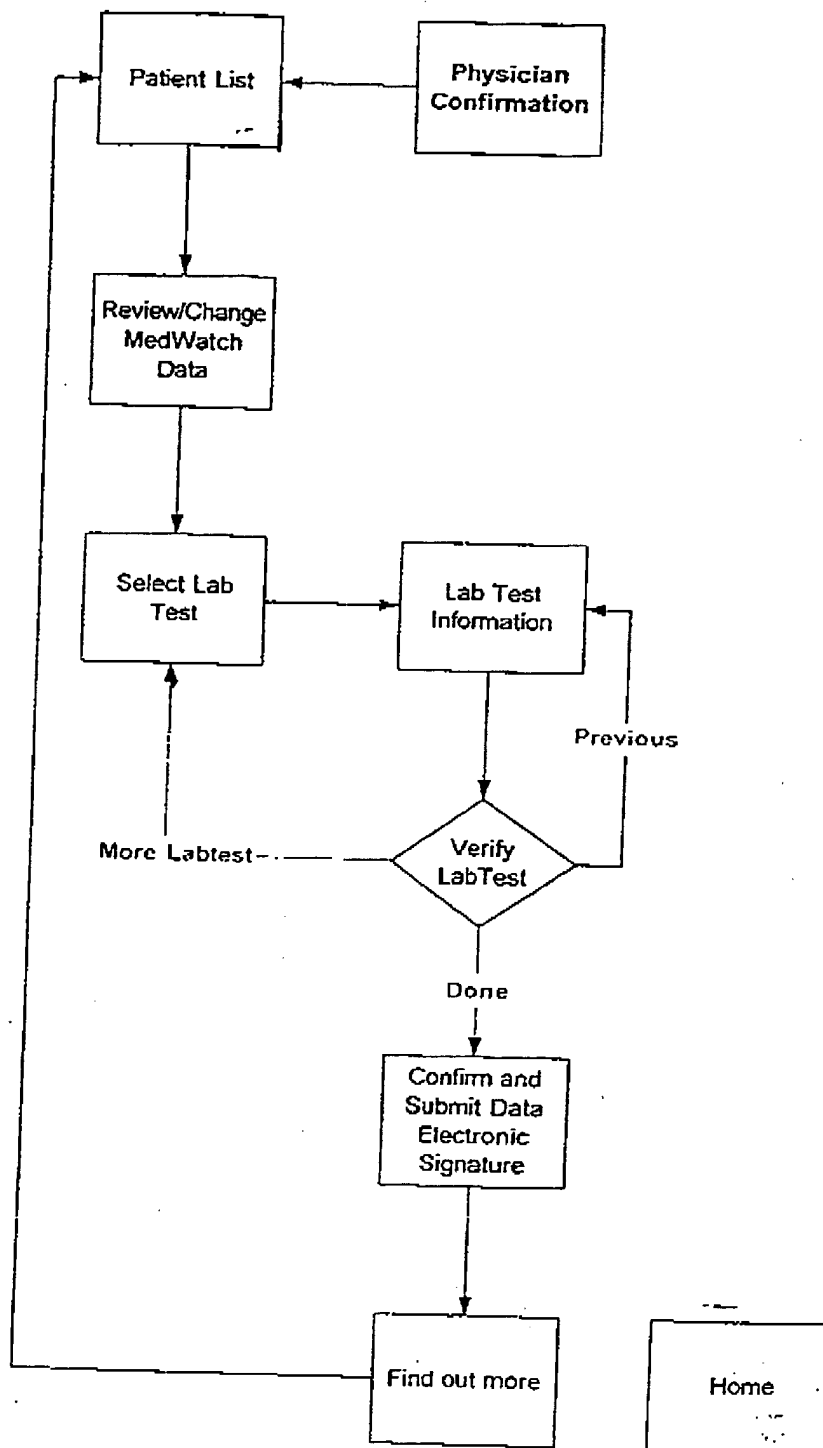


FIG. 3C



# Monitor Form

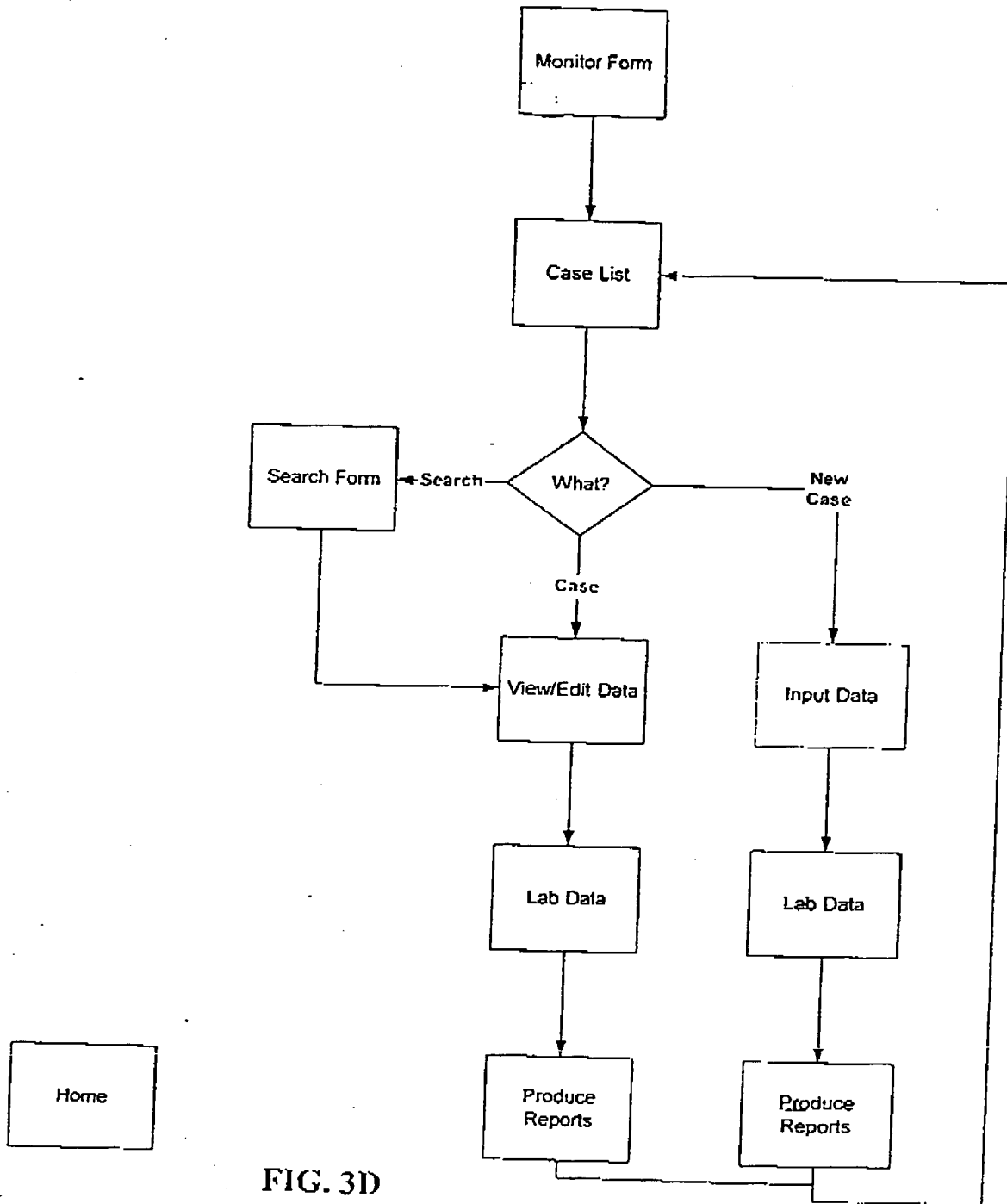
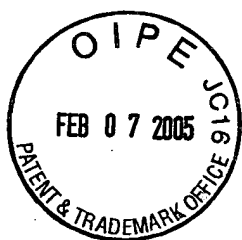


FIG. 3D



# Current Side Effects

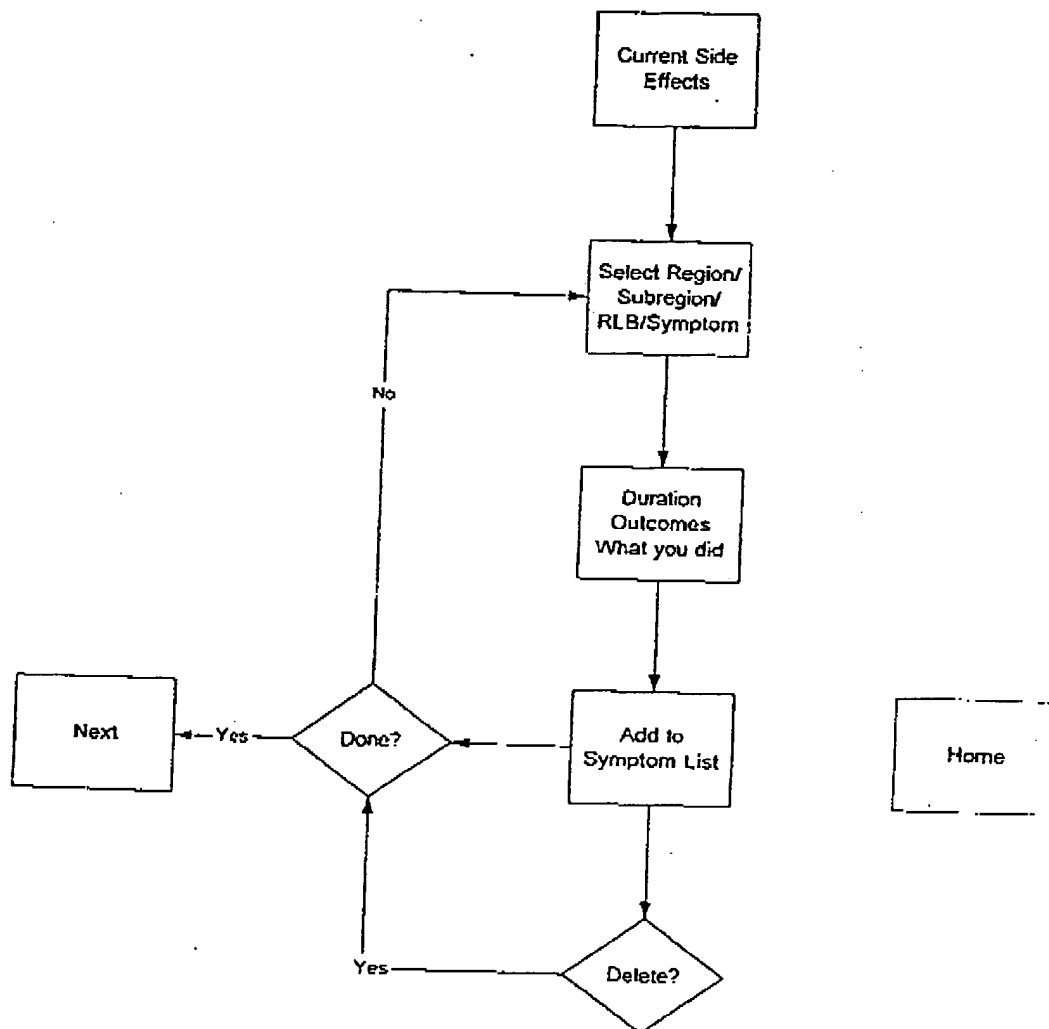


FIG. 3E





# Current Medication

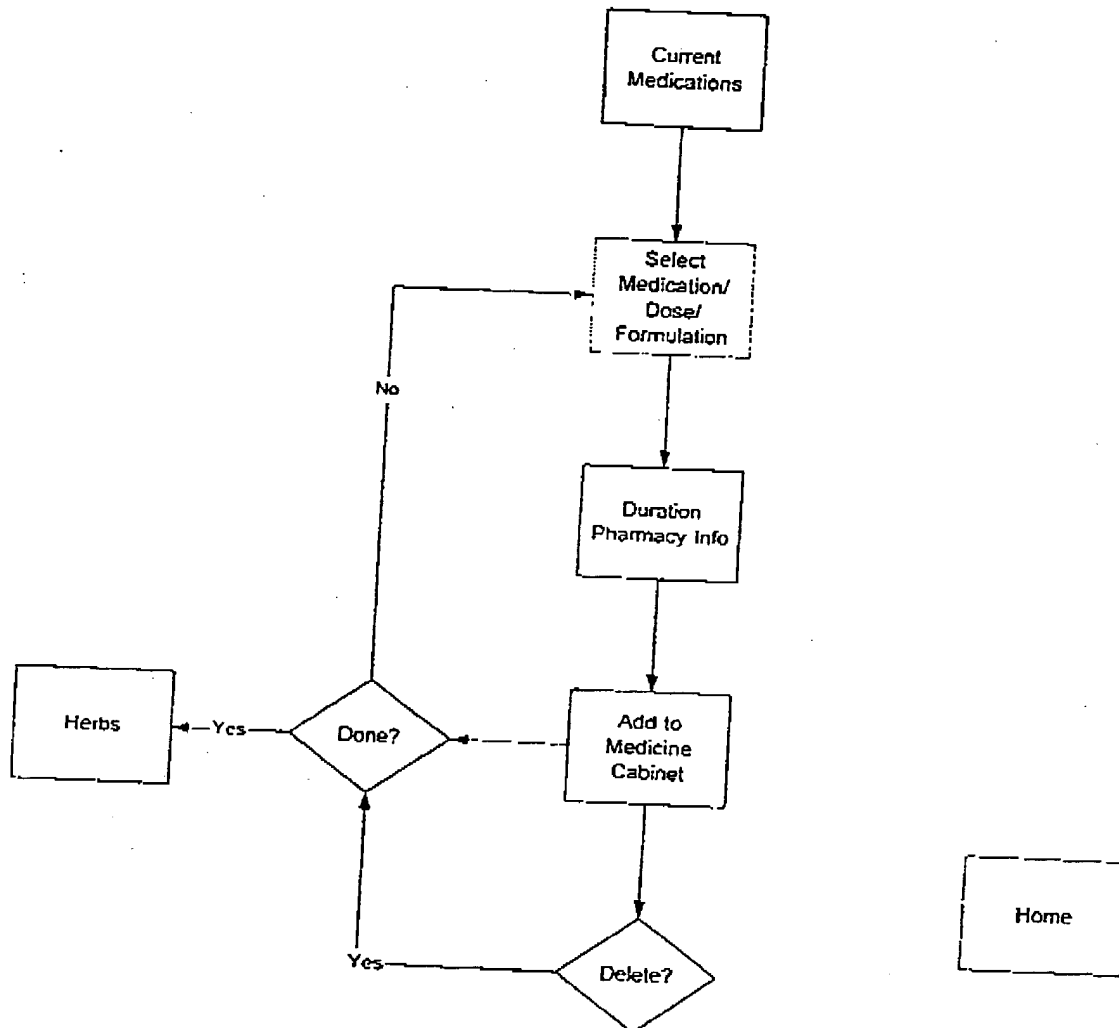


FIG. 3F



## Herbs and Nutritional Supplements

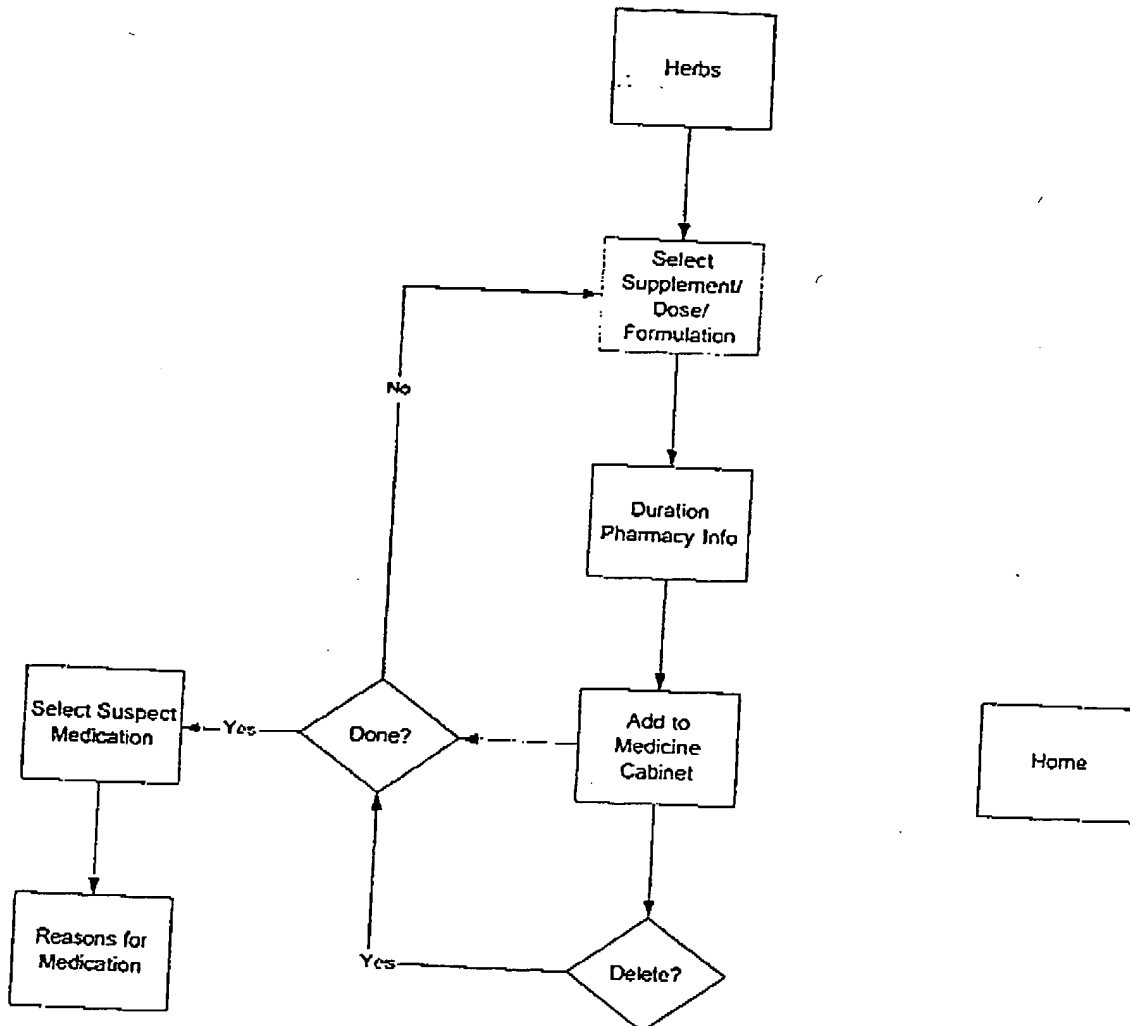
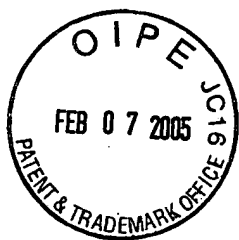


FIG. 3G



# Reasons for Medication

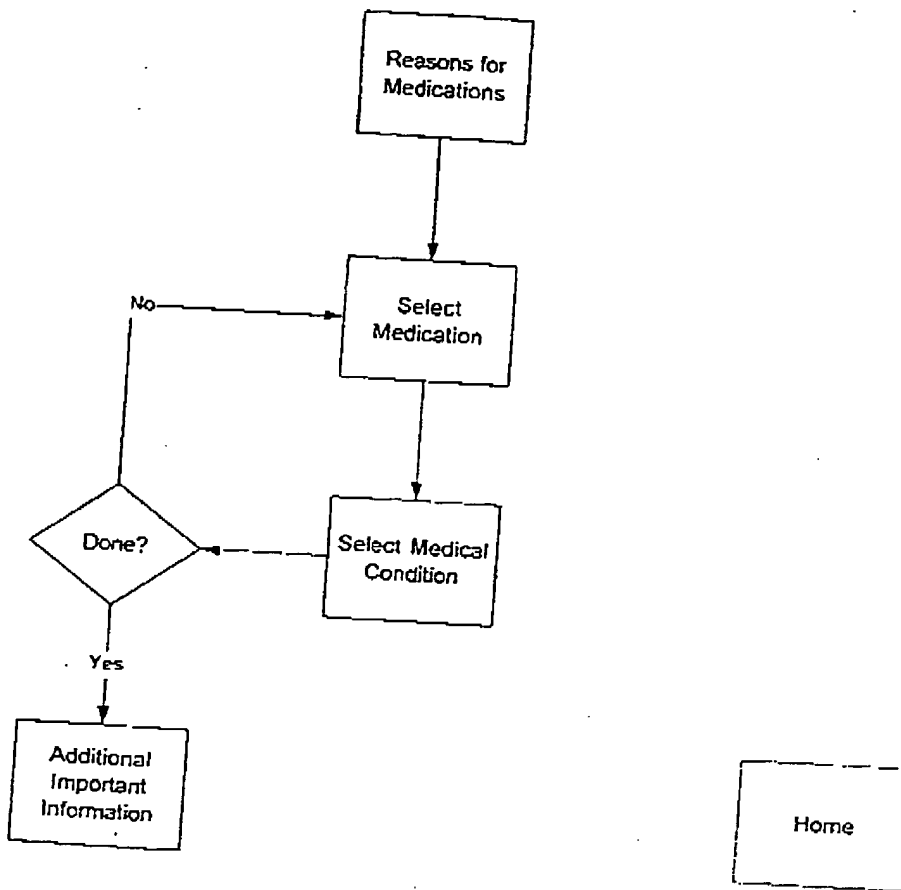


FIG. 3H



### Additional Important Information

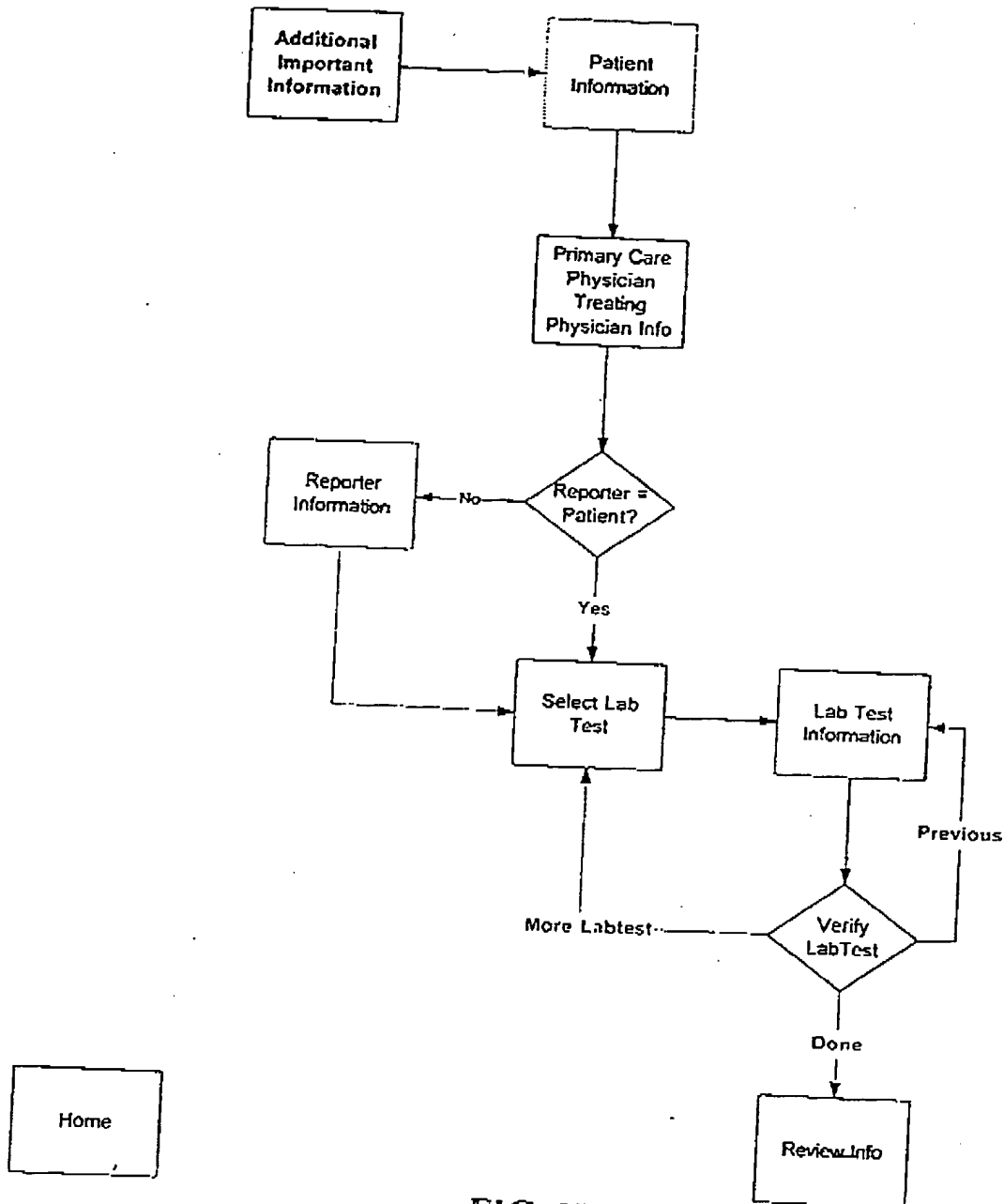


FIG. 3I



## Review Information and Find out More

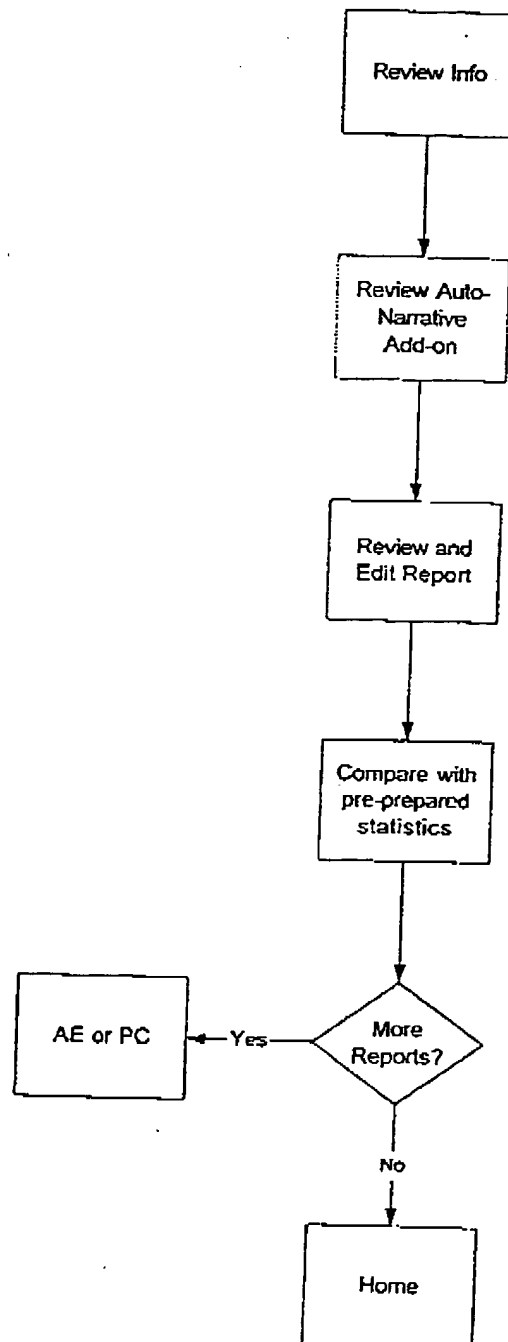


FIG. 3J



### Product Complaint

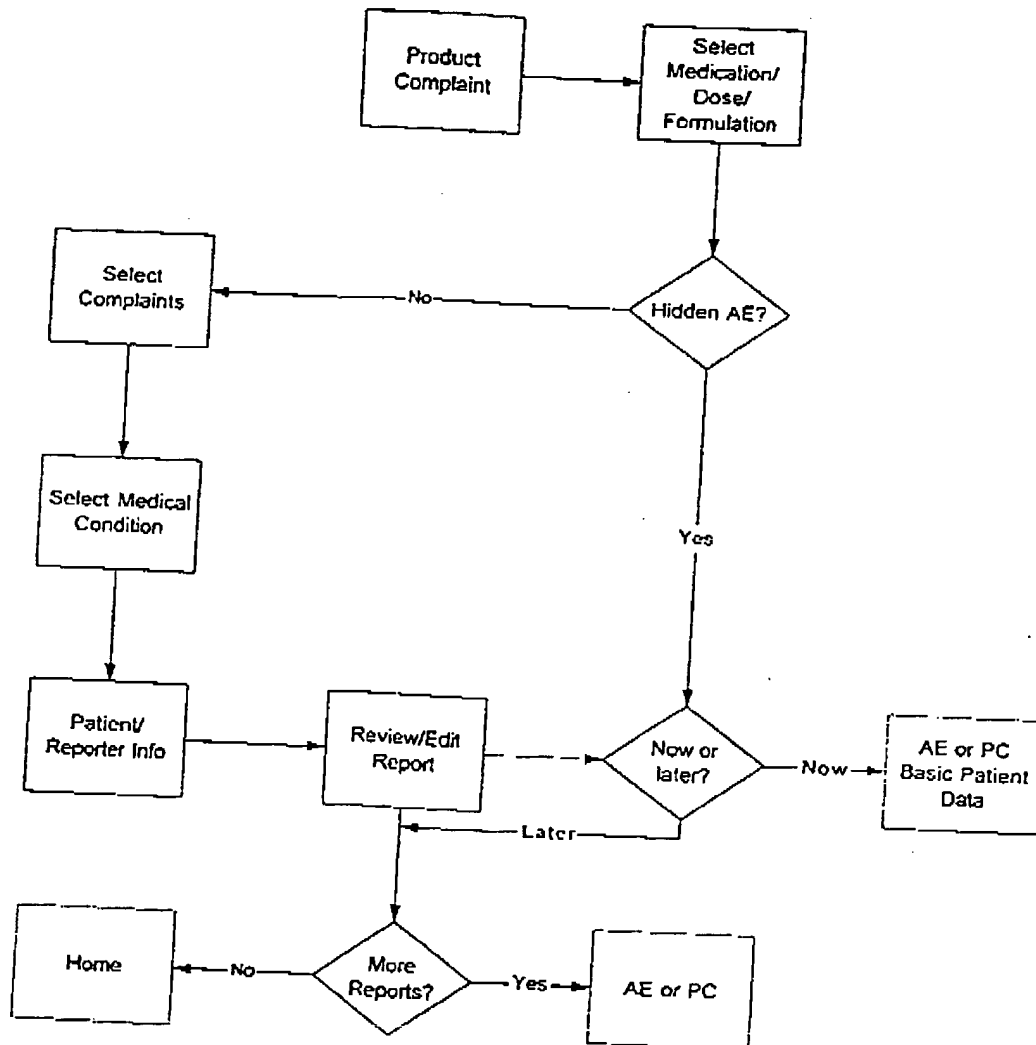


FIG. 3K



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Registration

## INFORMED CONSENT

IN ORDER TO COMPLETE THE REPORT, WE MAY NEED TO CONTACT YOUR PHYSICIAN. YOUR CONSENT TO CONTACT your physician is called informed consent. Only your physician and you will see the information you provide us.

☐ Accept ☐ (required to proceed)

# 1

Getting Started  
Login/Registration  
instructions

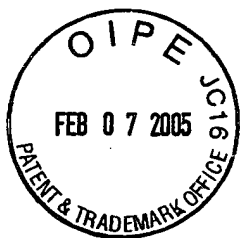
Who are you  
Side Effects and/or  
Product Complaints

This web portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can recreate it; 1)define a secret question (ex: What is my favorite football team) 2)define a secret answer (ex: the SF 49ers). Together these will identify you.

for this pilot, type the 8 digit registration code printed on your trial card.

First Name	<input type="text"/>
Last Name	<input type="text"/>
User ID	<input type="text"/>
Password	<input type="text"/>
Password again	<input type="text"/>
Secret Question	<input type="text"/>
Secret Answer	<input type="text"/>
Phone Number	<input type="text"/>
E-mail	<input type="text"/>

FIG. 4





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Welcome to MyDrug Safety

### Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.

the  symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

- 1 Getting Started
  - Login/Registration instructions
  - Who are you
  - Side Effects and/or
  - Product Complaints

### userID and Password

User ID

Password

### Change your Password?

New Password

Repeat Password

FIG. 5





### The Patient/Physician Relationship

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

**1** Getting Started  
Login/Registration  
instructions  
Who are you  
Side Effects and/or  
Product Complaints

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?



FIG. 6

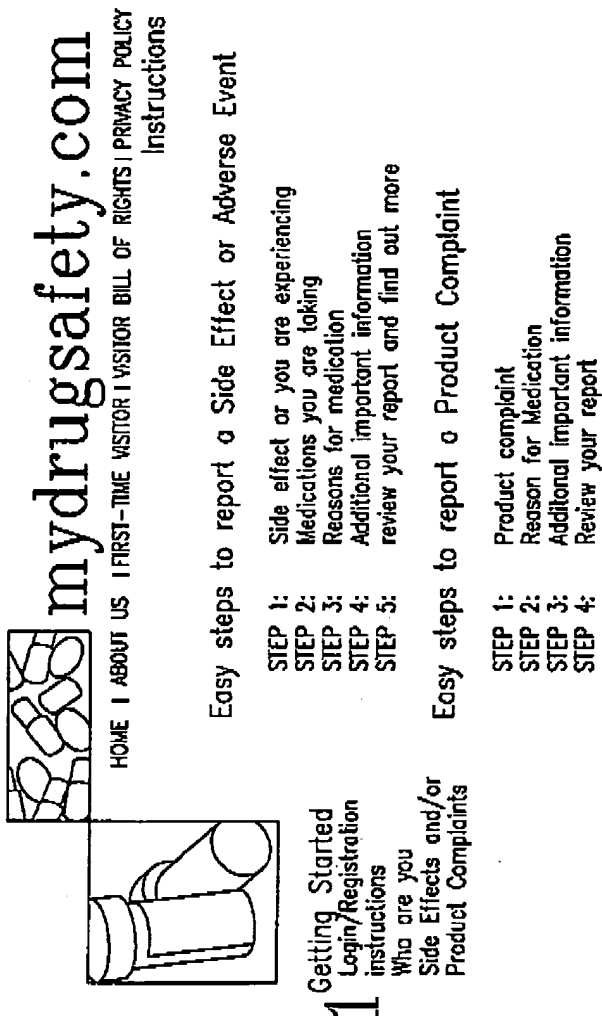
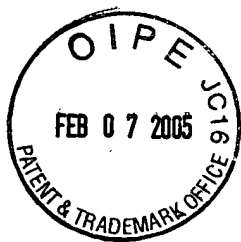
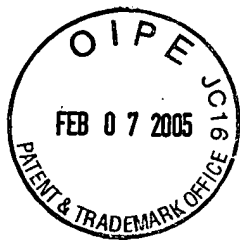


FIG. 7



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**Who Are You?**

②

☐ **Family member/spouse**  
☐ **Patient**  
☐ **Pharmaceutical Representative**  
☐ **Treating Physician**  
☐ **Choose One**

☐ **Other healthcare Professional**  
☐ **Choose One**

☐ **Someone else? Who?**

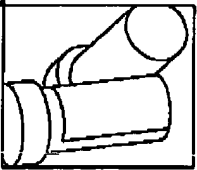
**1 Getting Started**  
 Login/Registration instructions  
 Who are you  
 Side Effects and/or  
 Product Complaints

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**FIG. 8**

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Adverse Event or Product Complaint?

What Do you Want to Report? ?

☐ AE ☐ PC

Adverse Reaction or a Side Effect you are having

Complaint about your medication

1 Getting Started  
Login/Registration  
Instructions

Who are you  
Side Effects and/or  
Product Complaints

Family Members Data:

Date of Birth  05-16-70 (mm-dd-yyyy)

or Age  11

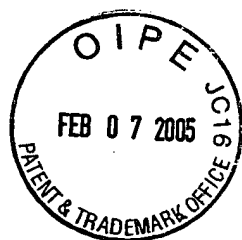
Height  51 feet  61 inches  
(ex: 5 feet 2 inches)

Weight  110 lbs

Male Female  
Pregnant ☒ YES

next

FIG. 9



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Adverse Event  
define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

To delete a symptom from highlight it and press  
Only when you have finished describing all your symptoms press

Delete Done

Click the region where the symptoms occur.

REGION Which area?:

or

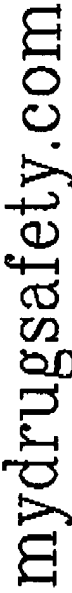
Anus  
Bladder  
Buttocks  
Cervix  
Groin  
Labia Minora/Majora  
Ovaries  
Rectum  
Uterus  
Vagina

- Getting Started
- Current Side Effects
  - What Symptoms
  - When Started
  - Ended
  - What Result
  - What you did
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More

FIG. 10a

PAGE 29/44 \* RCVD AT 2/7/2005 2:08:41 PM [Eastern Standard Time] \* SVR:USPTO-EFXXRF-2/2 \* DNIS:7464000 \* CSID:9739924643 \* DURATION (mm-ss):07-22





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Adverse Event  
define a Symptom

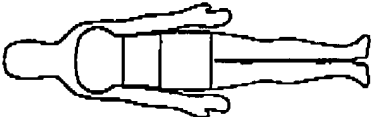
Describe your adverse event. Click on a body region and a list of its subregions will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Delete

Done

To delete a symptom from highlight it and press  
Only when you have finished describing all your symptoms press

Click the region where the symptoms occur.

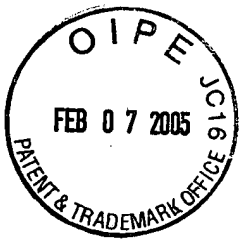
REGION	Which area?:
	Right-Buttocks
	Left-Buttocks
	Both-Buttocks

or

FIG. 10b

- 1 Getting Started
- 2 Current Side Effects
  - What Symptoms
  - When Started
  - Ended
  - What Result
  - What you did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

PAGE 30/44 \* RCVD AT 2/7/2005 2:08:41 PM [Eastern Standard Time] \* SVR:USPTO-EFXRF-2/2 \* DNIS:7464000 \* CSID:9739924643 \* DURATION (mm-ss):07-22



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Adverse Event

define a Symptom

FIG. 10c

Describe your adverse event. Click on a body region and a list of its symptoms will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Click the region where the symptoms occur.	REGION Which area?	SYMPTOM What symptom?	To delete a symptom from highlight it and press Only when you have finished describing all your symptoms press
 or	Buttocks	Hip Pain	<input type="button" value="Delete"/> <input type="button" value="Done"/>
		When did it start? (mm-dd-yyyy) When did it end (mm-dd-yyyy) OR How Long did it last? YEAR MONTH DAY It is still there? <input type="checkbox"/> yes <input type="checkbox"/> no RESULT What was the result of this event? <input type="checkbox"/> Hospitalized under 24 Hours <input type="checkbox"/> Hospitalized over 24 Hours <input type="checkbox"/> Disability	<input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to _____ <input type="checkbox"/> Switched Medication to _____ <input type="checkbox"/> Did it help? <input type="checkbox"/> Took medication again and effect came back <input type="checkbox"/> Took something for it. What? _____

1 Getting Started

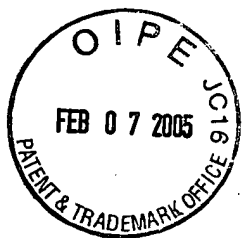
2 Current Side Effects  
What Symptoms  
When Started Ended  
What Result  
What you did

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More



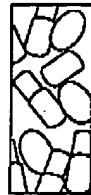
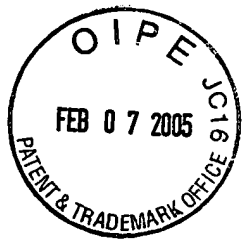
General Body		<input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died <input type="checkbox"/> (mm-day-yyyy) Other <input type="checkbox"/>	Did it help? <input type="checkbox"/> YES Did something else <input type="text"/>	Add Symptom to list
--------------	--	---	--	---------------------

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Help  
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FIG. 10d



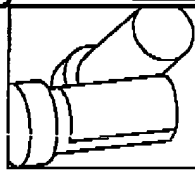


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## What Medication Are You Taking?

### Medication



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
  - Medications
  - Herbs and Supplements
  - suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More


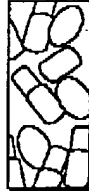
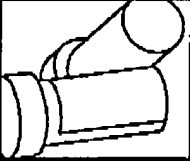
Your medicine Cabinet  <div style="float: right;"> <input type="button" value="Delete"/> <input type="button" value="Done"/> </div>	
To delete a medication from the list highlight it and press when your current Medication list is complete press	
Medication: Lamisil Dose: 1% Formulation: CREAM Frequency: 0 times a Day	How Long <input type="text"/> YEAR <input type="text"/> Start <input type="text"/> (mm-dd-yyyy) End <input type="text"/> (mm-dd-yyyy) Still on it optional info Lot # of drug? if present <input type="text"/> What Pharmacy did you purchase it at? <input type="text"/> Name <input type="text"/> Zipcode <input type="text"/> <input type="button" value="Add to Medicine Cabinet"/>

FIG. 11



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What Medication Are You Taking?  
Suspect Medication

Please select the medication(s) that you think may have caused the event>		?
Your Current Medications Are <input checked="" type="checkbox"/> Lamisil		
Previous	Next	

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications  
Medication  
Herbs and Supplements  
suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

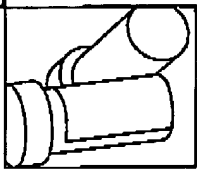
FIG. 12



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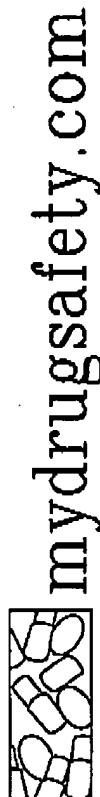
**What Medication Are You Taking?**  
Herbs or Nutritional Supplements



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications  
Medications  
Herbs and Supplements  
Problem Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<p>②</p> <p><b>Your Current Medications</b></p> <p>Your Current Medications &amp; medicine1 &amp; medicine1</p>		<p><b>HOW LONG</b></p> <p>number of days 1</p> <p>Start mm-dd-yy</p> <p>End mm-dd-yy</p> <p><input type="checkbox"/> Still on it optional info</p> <p>Lot # of supplement? if present</p> <p>What Pharmacy did you purchase it at?</p> <p>name zipcode</p>	
<p>Tell us what herbs or other supplements you are taking. click letter to choose from list.</p> <p>ABCDEF GHIJKL M NOPQRSTU VWXYZ</p> <p>Pick one:</p> <p>Select a medication 1</p> <p>Not on the list? Enter below</p>		<p><b>Add to Medicine Cabinet</b></p> <p>Need To delete a medication from your current list? Highlight it and press</p> <p>Delete</p> <p>when your current medication list is complete press</p> <p>Done</p>	

FIG. 13



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Adverse Event

What Are You Taking Your Medication For?

What condition are you taking your medication for? click on your medication and a list of its associated condition/disease will appear. select the appropriate one. Repeat for each medicine in the list. ?

Your Medication List				Medical Condition
Medication	Formulation	Dose	Frequency (Times a day)	
Lamisil	Cream	1%	4	<div>Select only one</div> <div>Not on this list?...Enter below</div> <div></div>

Previous

Next

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

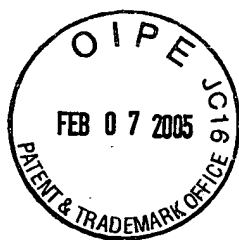
6 Review Info &amp; Find Out More

Help

{helpscreens}

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FIG. 14A



# PatientPort

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Adverse Event  
Lab Results

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
  - Patient Information
  - Physician Information
  - Lab Test Results
- 6 Review Info & Find Out More

Tell us what tests were done.  
Click letter to choose from list.

Then Select the appropriate test and method for the specimen. Standard values for the test will be presented with an indicator for whether the patient values are within range or out of range.

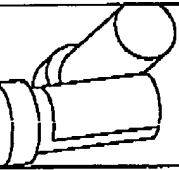
?

ABCDEFGHIJKLMN O PQRSTU VWXYZ

Test	Specimen	Method	Min-Max	test Value	Measurement Time & Date	Status of Test
Albumin	Serum	Colimentry	3.5-5.0 g/dl	dd <input type="text"/> <input type="text"/> mm <input type="text"/> <input type="text"/>	g/dl <input type="text"/> <input type="text"/> time <input type="text"/> <input type="text"/> year <input type="text"/> <input type="text"/>	<input type="radio"/>
Multiple test values at this date?						
Aldolase				dd <input type="text"/> <input type="text"/> mm <input type="text"/> <input type="text"/>	g/dl <input type="text"/> <input type="text"/> time <input type="text"/> <input type="text"/> year <input type="text"/> <input type="text"/>	<input type="radio"/>
Multiple test values at this date?						
Aldosterone				dd <input type="text"/> <input type="text"/> mm <input type="text"/> <input type="text"/>	g/dl <input type="text"/> <input type="text"/> time <input type="text"/> <input type="text"/> year <input type="text"/> <input type="text"/>	<input type="radio"/>
Multiple test values at this date?						
Alkaline				dd <input type="text"/> <input type="text"/> mm <input type="text"/> <input type="text"/>	g/dl <input type="text"/> <input type="text"/> time <input type="text"/> <input type="text"/> year <input type="text"/> <input type="text"/>	<input type="radio"/>
Multiple test values at this date?						
Phosphatase				dd <input type="text"/> <input type="text"/> mm <input type="text"/> <input type="text"/>	g/dl <input type="text"/> <input type="text"/> time <input type="text"/> <input type="text"/> year <input type="text"/> <input type="text"/>	<input type="radio"/>
Multiple test values at this date?						

Next

FIG. 14b



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Adverse Event Product Complaint  
Check your record

this Report

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More
  - Review narrative
  - Review Your Info
  - Other Similar Reports to the FDA

1			2
<p>A -30year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking lamisil 1% CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event [verbalim or reported] term/symptom (R/L/B) on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].</p> <p>The patient was also taking [prescription medication, over-the-counter or nutritional products; concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long</p>			

Anything to add?

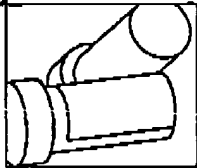
1		2
<p>Blablabla</p>		

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FIG. 15

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 Review Your & Who Record  
 Summary Report  
 pat1 patlast

?

Review and Edit your report,

Report is complete

Type over text to edit and only when complete press  
 A. Patient Information

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info &amp; Find Out More

Review narrative  
 Review Your Info  
 Other Similar Reports  
 to the FDA

Patient Name pat1 patlast

Date of Birth 06-16-70

Age at Event -30

Gender Male Female

Pregnant? Yes No Unknown

Weight 110 Lbs

Height 51 feet 61 inches

(ex: 5 feet 2 inches)

A. Adverse Event Results

☐ Died On (mm-day-yyyy)☐ Hospitalized Less than 24 Hrs☐ Hospitalized over 24 Hrs☐ Disability☐ Congenital Anomaly☐ Intervention needed☐ Life threatening☐ Other

Date of Event (mm-dd-yyyy)

Date of Report 01-23-2001 (mm-dd-yyyy)

FIG. 16a



Description					
<div> <div>Event Abated?</div> <div>Event Reappeared?</div> <div>C. Suspect Medications</div> <div>Drug Name</div> <div>Lamisil</div> </div>		<div> <div>oYes oNo oUnknown</div> <div>oYes oNo oUnknown</div> </div>			
		<div> <div>Dose</div> <div>1%</div> </div>		<div> <div>Therapy Dates/Duration</div> <div>From 07-01-2000 to 01-01-2001 Duration:1</div> </div>	
<div> <div>D. Concomitant Medication</div> <div>Drug Name</div> </div>		<div> <div>Dose</div> </div>		<div> <div>Therapy Dates/Duration</div> </div>	
				<div>Reason</div> <div>Disease 2</div>	

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 {helpscreens}

FIG. 16b

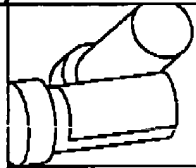




# PatientPort

HOME | Wer wir sind | Erstmaliger Benutzer | Datenschutz | Logout

## Arzneimittel-Nebenwirkungen definieren Sie Das Symptom



- Start**
- 1 Login/Registrierung**  
Bedienungsanleitung wer sind Sie?  
Arzneimittel-Nebenwirkung oder Beschwerde über das Arzneimittel
  - 2 Arzneimittel-Nebenwirkung**  
Ihre Symptome  
Beginn und Ende  
Direkte Auswirkungen  
Gegenreaktionen
  - 3 Ihre Medikamente**  
Medikamente  
Andere Medikamente  
Heilkräuter & Vitamine
  - 4 Weshalb nehmen Sie**

**FIG. 16C**

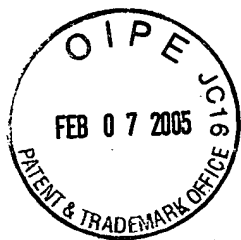
<p>Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu Beschreiben. Klicken Sie bitte eine Körperregion an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein symptom aus der präsentierten liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.</p>		<p><b>Kopf</b> Klicken Sie bitte die Region, in der Ihr Symptom sich aussart.</p>		<p><b>SYMPTOM</b> Ihr Symptom</p>		<p><b>DAUER</b></p>		<p><b>WAS UNTERNAHMEN SIE DAGEGEN?</b></p>	
<p><b>AUGEN</b></p>		<p><b>VERENGTE PUPILLEN</b></p>		<p>Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage 1 Besteht das Symptom immer noch? <input type="checkbox"/> JA</p>		<p><input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stopppte die medikamenten Einnahme Reduzierte die medikamenten Dosis auf <input type="checkbox"/> Wechseltte das Medikament auf</p>		<p>Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahn das Medikament wieder und der Effekt erschien wieder</p>	

Ihre Symptome  
Augen, verschwommene Sicht  
Augen, verengte Pupillen

LOSCHEN

FERTIG

Um ein Symptom zu löschen, klicken Sie bitte und drücken Sie. Erst wenn Sie alle Ihre Symptome abschließend beschrieben haben, drücken Sie bitte



Hospitalisierung unter 24 Std?	Nahm ein Gegenmittel. Was?
SYMPTOM ZUR LISTE HINZUFÜGEN	

**5** Zusätzliche  
Informationen  
patienten daten  
Arzte-Daten

**6 Bestätigen Sie Ihre Daten**  
Ihr generierter Bericht  
Alle Ihre Daten  
Vergleich mit anderen  
Berichten der FDA

FIG. 16d

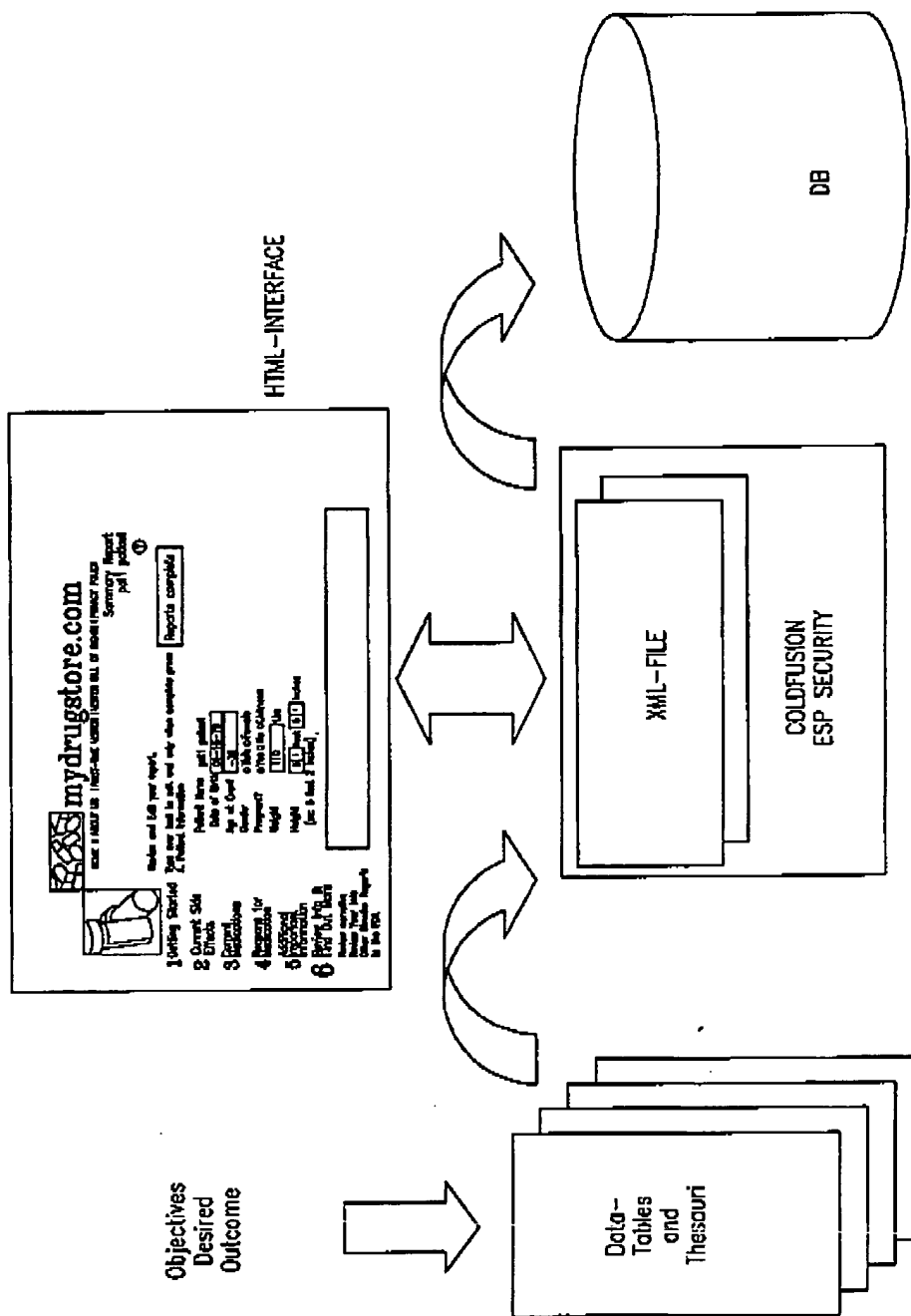
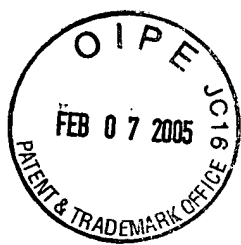
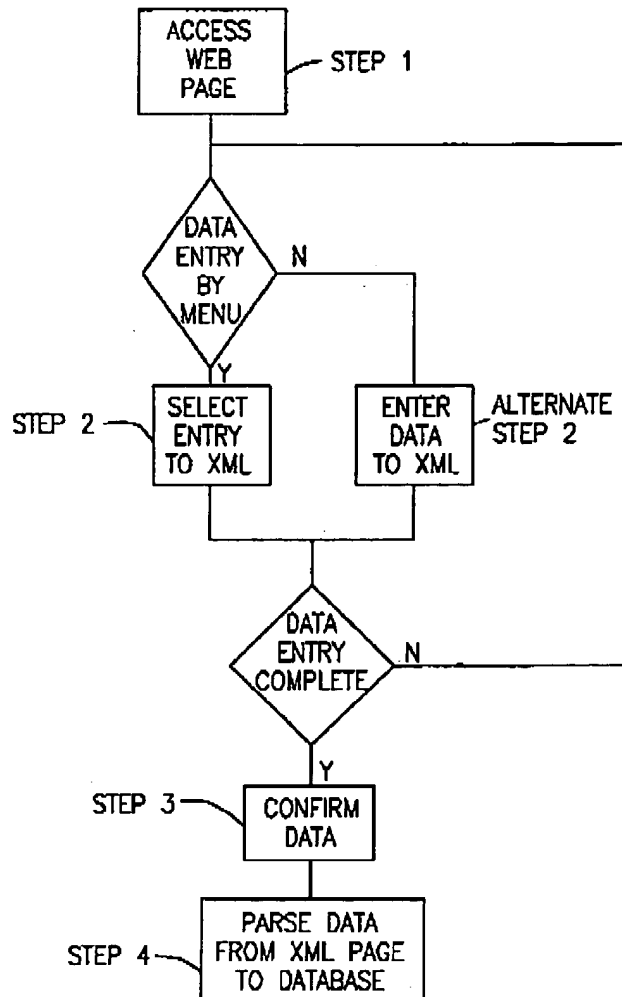


FIG. 17

*FIG. 18*